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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/501,698 | 02/03/2005 | Yasuyoshi Ueda | 5404/81 | 2912 |

7590 03/04/2008

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| EXAMINER | |
|---|---|
| SINGH, SATYENDRA K | |
| ART UNIT | PAPER NUMBER |
| 1657 | |
| MAIL DATE | DELIVERY MODE |
| 03/04/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/501,698 | UEDA ET AL. | |
| | Examiner | Art Unit | |
| | SATYENDRA K. SINGH | 1657 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *29,31,33,34,36,39-41,46,49,51 and 61-77* is/are pending in the application.

4a) Of the above claim(s) *1,2,4,8,12,13,15,17,20 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,31,33,34,36,39-41,46,49,51 and 61-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

Applicant's response (and amendments to claims) filed with the office on December 10th 2007 are duly acknowledged.

Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61 and 62-77 (the elected invention of group III; as currently amended) are examined on their merits in this office action.

The following action contains new grounds of rejections necessitated by applicant's current amendments to the pending claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51 and 61-77 (as currently amended) are/remain rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 as amended recites (see instant claims 29 and 62, in particular) the limitation of "**fat or oil and/or a polyol**" without providing any guidance as to how to interpret the composition as claimed. It is noted that claim can be interpreted to comprise reduced coenzyme Q10, a polyglycerol fatty acid, and any one of these combinations as follows:

-a fat and oil and a polyol, or a fat and oil or a polyol (as was previously presented), and can now be interpreted as comprising reduced coenzyme Q10, a polyglycerol fatty acid and either:

-a fat or oil and a polyol, or

-a fat or oil or a polyol (as currently amended; which will only require three components, coenzyme Q10, a polyglycerol fatty acid ester, and either a fat, or oil, or a polyol).

Therefore, it is unclear as to what exactly is encompassed by the limitations as presented in the composition of claim 29. Similarly, claim 62 as amended seems to recite said limitation "fat or oil" in an unclear Markush group containing various exemplifications, including "modified fat and oil", which renders the invention indefinite. Appropriate explanation/correction is required.

It is also noted that in the absence of a clear guidance from applicants (for the amended composition comprising "fat or oil" as recited in the claim 29; see remarks, page 9, paragraphs 1-3, in particular) the instant claim could also be interpreted as broadening the scope of the composition as claimed, and could potentially be treated as introducing "new matter". Appropriate explanation/correction is required.

2. Claim 63 (as currently amended) is/remains rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim 63 as amended (depends from the broader claim 29) recites the limitation of "wherein the weight ratio of the fat or oil to the total weight of fat or oil and polyol is not lower than 1/10", which is confusing. Since, the broader claim 29, as amended, still presents polyol as an **optional** component (see the recitation in claim 29 as currently amended, "fat or oil **and/or** polyol", i.e. only requires the presence of either fat, or oil, or a polyol), it is unclear as to how one of ordinary skill would understand and meet the limitation of

the invention of claim 63 in the absence of said polyol, as currently presented by applicants. Appropriate explanation/correction is required.

Applicant's assertion (see remarks, page 9, 2nd and 3rd paragraph, in particular) that:

> "The listed claims were each rejected under 35 U.S.C. § 112 for alleged indefiniteness. Failure to particularly point out and distinctly claim various features of the invention are alleged by the Examiner in most cases, and indefiniteness based on improper antecedent bases in others. Several informalities are also noted by the Examiner.
> Each of the aforelisted claims rejected for indefiniteness have been amended to overcome these criticisms. Likewise, formal objections have been obviated by amendment."

Is not found to be persuasive because the broader claim 29 still presents "a polyol" as an optional component, and thus the claimed composition does not require its presence as recited in instant claim 63.

2. Claim 63 as currently amended recites the limitations "**the** weight ratio" and "**the** total weight" in line 3 of the amended claim. There is insufficient antecedent basis for this limitation in the broader claim 29.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51 and 61-77 (as currently amended) are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (WIPO document, WO 01/52822 A1; IDS) in view of Motoyama et al (US 4,751,241; [A]).

Claims are generally drawn to a **reduced coenzyme Q10-containing composition** comprising reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat and oil (in the absence of an explicit definition in the instant specification, taken as either fat or oil, as recited in instant claim 62) and/or a polyol (see instant claims for detailed recitations).

Chopra (IDS) discloses a reduced coenzyme Q10-containing composition (see abstract, claims, and examples I-X, in particular) comprising reduced coenzyme Q10, a fat or oil, and a polyol (such as glycerol or other polyhydric alcohols). Chopra discloses reduced coenzyme Q10-containing compositions in various forms including oral dosage forms such as soft capsules, etc. which are "substantially ubiquinone-free", and incorporate reducing agents, oils or fat, polyols, and surfactants (see WIPO document, page 14, 5th paragraph, and examples I-X, in particular). Chopra discloses that such compositions may contain soybean oil, sunflower oil, safflower oil, rapeseed oil, fish oil, medium chain triglycerides, phospholipids (as recited in instant claim 62; see Chopra, various embodiments), surfactants (such as Tween or Span; see examples I, III, IV, VI, in particular), reducing agent such as vitamin C or ascorbyl palmitate (see Chopra,

examples, and claim 2, in particular), and can be prepared or stored in a deoxygenated (such as prepared and sealed under nitrogen gas; see Chopra, page 21, example I, last paragraph, in particular).

However, a reduced coenzyme Q10-containing composition comprising **polyglycerol fatty acid ester** (as recited in instant claims 46 and 70-72) is not explicitly taught by the composition of Chopra (IDS).

Motoyama et al [A] discloses polyglycerol fatty acid esters (see abstract, summary of the invention, columns 1-2, in particular) such as diglycerol monooleate (see column 2, lines 23-30, in particular) to be used as emulsifying agents for drugs that are very slightly soluble in water (including ubiquinones, CoQ10; see column 2, lines 38-56, in particular) in order to enhance the absorption and thus bioavailability of said drugs (i.e. in a pharmaceutical composition) in the digestive tract when administered using oral dosage forms such as soft capsules (see columns 4-5, and examples).

Therefore, it would have been obvious to a person of ordinary skill in the pharmaceutical composition art to modify the reduced coenzyme Q10-containing composition of Chopra (IDS) such that it contains (in addition to the surfactants such as Tween or Span) an emulsifying agent such as polyglycerol fatty acid ester as explicitly taught and exemplified by Motoyama et al.

One of ordinary skill in the art would have been motivated at the time of invention to make such modification in the composition taught by Chopra (IDS) in order to obtain a better reduced coenzyme Q10-containing composition (having an enhanced absorption and bioavailability in the gut) as suggested by Motoyama et al, with a reasonable expectation of success. The claimed subject matter as currently presented

by applicants fails to patentably distinguish over the state of the art as represented by the cited prior art references. Therefore, the claims are properly rejected under 35 U.S.C. § 103(a).

With regard to the limitations of claims 33 (content of fat or oil and/or polyol, on percent basis), 36 (content of ascorbic acid, on percent basis), 41 (the content of surfactant), 63 (ratio of fat and oil to fat and oil and polyol by weight), 64 (content of reduced CoQ10, on percent basis), and 67 and 68 (the content of polyglycerol fatty acid ester by weight, on percent basis), it is to be noted that given the detailed disclosures of all the components and their amounts used for various preparations or dosage forms by Chopra and Motoyama et al (as discussed above), the adjustments to the contents and ratio of various components used in the composition would have been clearly obvious to a person of ordinary skill in the pharmaceutical art, and would involve routine optimization in order to achieve a better and stable composition containing reduced Coenzyme Q10. The claimed limitations of instant claims 46, 49, 51 and 69 are taken to be inherent in the composition taught by the cited prior art references as discussed above.

*As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*

*As per PPEP 2144.05 (R-3): In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). "[ A ] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).*

*As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).*

*As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).*

### *Response to Applicant's Arguments*

Applicant's arguments filed with the office on December 10th 2007 (as they pertain to the prior art rejection of record) have been fully considered but they are not persuasive for the following reasons of record. Applicants argue the following (see remarks, page 9-10, in particular):

> "With respect to the 35 U.S.C. § 103(a) rejections, the present invention relates to a reduced coenzyme Q10 containing composition which comprises reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat or oil and/or a polyol. This composition has the good stability of reduced coenzyme Q~0 and the high-level absorbability in the living body thereof, simultaneously. Specifically, the addition of the polyglycerol fatty acid ester enhances absorbability of reduced coenzyme Q~0 in the living body and hardly inhibits the reduced coenzyme Q10-stabilizing effect of the fat or oil and/or polyol.
> As described on page 5, lines 14-24 in the specification, the applicants discovered that while the addition of Tween and Span species (surfactants (emulsifiers)) in wide use markedly decreases the above-mentioned reduced coenzyme Q10 stabilizing effect of fat or oil and/or polyol, the addition of polyglycerol fatty acid esters surprisingly has little influence on the stabilizing effect of fat or oil and/or polyol.
> On the other hand, Chopra relates to a composition comprising ubiquinol and an amount of a reducing agent effective to reduce or eliminate the oxidation of that ubiquinol to ubiquinone; that composition further comprising an amount of a surfactant or vegetable oil or mixtures thereof and optionally, a solvent, effective to solubilize said ubiquinol and said reducing agent. As the Examiner recognizes, Chopra does not disclose the reduced coenzyme Q10-containing composition comprising the polyglycerol fatty acid ester of the present invention.
> Motoyama relates to a pharmaceutical composition which provides a high-degree of bioavailability of cyclandelate when administered orally. The composition consists of a mixture of (a) a polyglycerol ester of an unsaturated fatty acid or mixtures thereof and (b) cyclandelate. Motoyama only describes that the polyglycerol ester of an unsaturated fatty acid is used in order to facilitate the absorptivity of the drug. Thus, Motoyama neither discloses nor suggests that the

> polyglycerol ester of an unsaturated fatty acid hardly inhibits the reduced coenzyme Q10-stabilizing effect of fat or oil and/or polyol.
> It is thus abundantly clear that neither Chopra nor Motoyama disclose nor suggest that the composition can have the good stability of reduced coenzyme Q~0 and the high-level of absorbability thereof in the living body by the constitution of the present invention. Accordingly, the present invention could not have been suggested by one skilled in the art from the combination of Chopra and Motoyama, except perhaps by chance or hindsight."

In response, it is noted that the claimed composition (as currently amended) is directed to "a reduced coenzyme Q10-containing composition" comprising "reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat or oil and/or a polyol", the components of which are all disclosed in the cited prior art references of Chopra in view of Motoyama et al (as discussed in the obviousness rejection of record, above). The applicant's argument regarding the use of surfactants (i.e. Tween or Span species as emulsifiers) and associated effects on the stability of claimed composition is not found to be persuasive because applicant's claim 40 is directed to such composition that requires said surfactants/emulsifiers. Moreover, claim 29, as currently amended, does not require the presence of any surfactant/emulsifier, as currently argued by applicants.

It is further noted that instant claims (see claims 29, 46 and 70, in particular) only require the presence of "a polyglycerol fatty acid ester" such as a "diglycerol fatty acid ester", and not a "polyglycerol fatty acid ester of an unsaturated fatty acid", as argued by applicants (see remarks, page 10, 3rd paragraph, in particular). However, Motoyama et al disclose the use of a "polyglycerol fatty acid ester of an unsaturated fatty acid" such as "diglycerol monooleate" (see discussion of the prior art, above) for stabilization of compositions containing drugs such as Coenzyme Q10 (see Motoyama et al, column 2, lines 55-56, in particular), which would clearly motivate an artisan of ordinary skill to use

diglycerol monooleate, and therefore, the obviousness rejection of record is properly made and maintained.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51 and 61-77 (as currently amended) **are/remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-19 of copending Application No. 11/586511 (filed in US on 10/26/2006; common inventors; and same assignee, Kaneka Corporation, Japan). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application also claims a reduced coenzyme Q10-containing composition (processed as an oral dosage form) comprising reduced coenzyme Q10, oil and fat, a polyglycerol fatty acid ester, along with a reducing agent, ascorbic acid. Since the two sets of composition claims are very similar (i.e. co-existent) in their scope, an obviousness-type double patenting rejection is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Response to Arguments*

Applicant's arguments regarding the ODP rejection of record have been fully considered but they are not persuasive for the following reasons of record. Applicants argue the flowing:

> "With respect to obviousness-type double patenting rejections, claims 16-19 of copending application No. 11/586511 relate to a stable composition comprising reduced coenzyme Q10. The composition comprises ascorbic acid or a related compound thereof together with the reduced coenzyme Q10, an oil or fat, a polyglycerol fatty acid ester with a polymerization degree of glycerol being no lower than 3 and/or a condensed ricinoleic acid polyglyceride. In contrast, the present application defines selective invention, in which more excellent stabilizing effect can be obtained by limitation of the polymerization degree of glycerol to no lower than 3. This is shown in Example 1, and Table 1 of the copending application. As such, the invention claimed in the present application is not obvious from that of the copending application."

In response, it is noted that claim 29 of the instant application is directed to a reduced coenzyme Q10-containing composition comprising reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat or oil and/or a polyol, which is deemed generic to the claim 16 of the co-pending application 11/586,511, and therefore, the two sets of claims are co-extensive in scope, and thus, the provisional ODP rejection of record is properly made.

***Conclusion***

**NO claims are allowed.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/Sandra Saucier/

Primary Examiner, Art Unit 1651